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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,139	01/28/2004	Stefan Schreck	ECV-5541DIVCON	1979
30452 7590 10/18/2007 EDWARDS LIFESCIENCES CORPORATION LEGAL DEPARTMENT ONE EDWARDS WAY IRVINE, CA 92614			EXAMINER MILLER, CHERYL L	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 10/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

HH

Office Action Summary

Application No.

10/766,139

Applicant(s)

SCHRECK, STEFAN

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 19, 21, 22, 24-26, 38, 39 and 43-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18, 19, 21, 22, 24-26, 38, 39 and 43 is/are allowed.
- 6) ☒ Claim(s) 44-53 and 55-58 is/are rejected.
- 7) ☒ Claim(s) 54 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 44-58 have been considered but are moot in view of the new ground(s) of rejection.

The applicant has argued that Cribier (US 6,908,481) does not disclose a valve that requires axial movement to connect the two components. The examiner disagrees. Axial movement, before, during or after expansion may occur, and when doing so, will lock the “hooks” into adjacent apertures in the outer frame base. Cribier’s inner stent subassembly is *capable* of being expanded and thereafter being moved axially toward the base until a barb/hook on the subassembly locks or snaps into an opening in the base (outer stent). Therefore, Cribier’s coupling members are capable of being coupled mechanically by axial movement after expansion. The applicant has further argued that Cribier does not disclose axially extending coupling members. The examiner disagrees. Hooks on one frame and apertures in the stent frame of the other frame are considered mutual coupling members (col.20, lines 33-38) each coupling member having an axial and transverse dimension, and extend in both directions, including the axial dimension, thus the coupling member are axially extending.

The applicant has argued that Garrison (US 6,425,916-regarding claim 44) does not leaflets spaced from the outflow rim of the base. The examiner disagrees. The applicant’s have claimed *two separate* components, the language of “after the leaflet subassembly has been mechanically coupled to the tissue-engageable base” is intended use language and Garrison’s valve need be only *capable* of such an orientation after coupling. Garrison (embodiment shown in figs. 1-30) discloses two separate components (6 and 8), they are *capable* of being attached to

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one another any at any location relative to one another. The surgeon has the capability of expanding or moving the inner subassembly (6) to his/her desired position relative base (8). The couple member on subassembly may be a coil (34) or barbs (100). Coils have a plurality of windings and may split, expand, thus some windings of a coil (34) are capable of locking into any of the smaller openings (14), including the larger opening 14 need outflow rim 20, which places the leaflets outside the outflow rim. Further, barbs (100) on inner subassembly may also be considered coupling members, which also may lock into any of the openings (14). Further, Garrison's embodiment shown in figures 32-38 clearly shows leaflets axially spaced from base 111 after coupling, see fig.38.

The applicant has also argued that Garrison (US 6,425,916-regarding claim 50) does not disclose axially extending coupling members. Hooks 100 or protrusions 34 on the subassembly and apertures 14 in the frame base are considered mutual coupling members each coupling member having an axial and transverse dimension, and extend in both directions, including the axial dimension, thus the coupling member are axially extending.

The applicant has also argued that Garrison (US 6,425,916-regarding claim 50) does not disclose a valve that requires axial movement to connect the two components. The examiner disagrees. This is intended use language and Garrison's valve need not show this, but need be only capable of such movement. Garrison's two separate component are capable of axial movement, and axial movement at anytime, including after expansion, will lock barbs or protrusions into the next adjacent opening 14, thus coupling the components. Axial movement, before, during or after expansion may occur, and when doing do, will lock the "barbs" or "protrusions" into adjacent apertures in the other frame. Couplers 34 and 100 are *capable* of

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engaging any of the openings 14, even after expansion. Axial movement is a method step or intended use language and Garrison's parts are capable of the claimed orientation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 50-53, 55, and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Cribier (US 6,908,481 B2, cited previously). Referring to claim 50, Cribier discloses a two part prosthetic heart valve (see figs.14-15 and respective portions of the specification) comprising a tissue-engagable base (10) that is expandable, and an expandable leaflet subassembly (10') including a support structure (stent frame 11 of 10') and three valve leaflets (see valve 14 with three leaflets shown in detail in fig.4b, located between struts 17) attached to the support at commissures (commissures being peaks of sinusoidal wave of stent frame; along line 20, seen in detail in fig.7; or at 19 in fig.6b), and further a plurality of axially extending discrete connectors (barbs and openings each have an axial dimension or height, thus have an extension in the axial direction) on the leaflet subassembly (hooks) and the tissue-engagable base (openings in stent frame 10 for hooks to engage; col.20, lines 33-38) that are joined/coupled by axial movement (see figs.15a-h; when moved axially, hooks will lock into adjacent stent apertures; when deployed axially adjacent one another, it is then *capable* of axial movement until a barb or hook engages an opening to lock/couple the two parts together).

Referring to claims 51-53, 55, and 56, Cribier discloses the base to be plastically expandable (col.9, lines 14-22; see fig.15a, 15b). Cribier discloses the support (stent frame 10') comprising a wireform (wire struts 11; seen in figs.14, 15) having alternating cusps and commissures (the zigzag sinusoidal wire mesh having peaks and troughs, which are considered by the examiner to be the "cusps" and "commissures"). Cribier discloses the wireform peaks and troughs to have connectors (hooks; col.20, lines 33-38). The connectors are joined by axial compression, see fig.15c-15f, wherein the subassembly is moving axially and radially to connect (snap in, upon expansion and axial movement) to the base.

Claims 44-53 and 55-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Garrison et al. (US 6,425,916, cited previously). Referring to claim 44, Garrison discloses a two part prosthetic heart valve (see in embodiment of figs.1-30) comprising an expandable tissue-engaging base (8) of a tubular body having an inflow end and outflow rim (20; see fig.8), a leaflet subassembly (6, 6C) comprising an elastic wireform support (26) that supports three heart valve leaflets (38; see fig.11, 34, 38; it is noted that the leaflets are not required anymore by the claim to be a component of the subassembly, they need only be supported by the subassembly wireform), the base and subassembly being separate components adapted to be stored separately (see figs.8, 10) that are *configured* to be coupled when implanted (*adapted* to be coupled by barbs or protrusions into openings or friction fit; see fig.9 for example). Applicant has claimed the positioning of the leaflets with respect to the base (axially spaced from the base) after they are mechanically coupled. Garrison's two parts are *capable* of being located in such relative positioning. That is, Garrison's connector on the subassembly (100 or 34) is adapted to connect

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into any opening 14 on the base (8), thus capable of the leaflets being positioned outside the tubular body. The surgeon that implants the two separate parts may expand each part at any desired location relative one another, the two parts are *capable* of having the spaced orientation claimed. Garrison has even shown the capability of being able to place the two parts at different positions relative one another, see figs.20, 27, 28, see col.10, lines 26-36. It is inherent that Garrisons subassembly connectors (100 or 34) are *capable* of being placed in the top outflow end openings 14, such that the leaflets are not located within the tubular body. Separate components are claimed, their positioning relative one another is intended use language and Garrison's valve is *capable* of such positioning.

Further with respect to claim 44, Garrison's embodiment shown in figures 32-38 may also apply wherein the base is considered (111) and the subassembly is considered (8D- it is noted that the leaflets are not required to be part of the subassembly anymore, all that is required by the claim is that the subassembly support leaflets, not necessarily comprise leaflets). Clearly the subassembly (8D) is a separate component from the base (111), configured to couple by members (34D, 108). The valve (6D) is shown axially displaced from the base (111) outflow rim after coupling (see fig.38).

Referring to claims 45-48, Garrison discloses a plastically-expandable base (8), see figs.3-4, col.2, lines 1-5, and an elastic wireform (26) subassembly (6) having cusps and commissures (see fig.10, 30). Garrison discloses the subassembly to mechanically couple to the base at a plurality of locations (all along the circumference, where each barb 100 or protrusion 34 is located is a different location; see figs.9, 30). Garrison discloses the base (8) to have

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mechanical coupling members (openings 14) and the subassembly (6) to have couple members (100 or 34).

Referring to claim 50, Garrison discloses a two part heart valve (see embodiment in figs.1-30) comprising an expandable base (8), an expandable leaflet subassembly (6) including a support (stent 26) and three leaflets (38) attached at commissures (see fig.10), and a plurality of axially extending (barbs 100, protrusions 34, and openings 14 are three dimensional and have a transverse and axial dimension, thus do extend axially) discrete mating connectors on each the base and subassembly (the base 8 has openings 14 in which protrusions 100 or 34 of the subassembly 6 engage; col.9, lines 64-67; col.10, lines 1, 16-24), wherein axial displacement after expansion actuates coupling of the components (this is intended use language and Garrison's valve need only be capable of doing such; Garrison's components are capable of coupling by axial displacement; when the subassembly is expanded axially spaced from the base or not fully expanded, it may then be moved axially and the barbs or protrusions will lock into the first opening they encounter, coupling the components upon axial movement. They are *capable* of engaging upon axial movement after expansion.

Referring to claims 51-53 and 55-57, Garrison discloses a plastically expandable base (8; col.2, lines 1-5; figs.3, 4), a subassembly comprising a wireform having cusps and commissures (peaks and valleys of stent 26; see fig.10), mating connectors (100) on the subassembly (6) located on the cusps and commissures (see figs.29, 30) and are joined to the base by axial compression, snap fit (will snap into openings 14 upon expansion after axially positioning). Garrison discloses one of the mating connectors (openings 14) to comprise a partial circle opening (seen in figs.8, 9, portions of openings 14 form a partial circle).

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Referring to claim 58, Garrison discloses a two-part valve (see embodiment in figures 32-38) comprising a tubular expandable base (111) having an inflow end and outflow rim and a leaflet subassembly (8D) including an elastic wireform (stent of 8D) supporting three biological leaflets (6D-the leaflets are not required by the claim to be part of the subassembly, it is only required that the subassembly support the leaflets-not comprise them), wherein the base (111) and subassembly (8D) are separate components adapted to couple (see figs.32-38) and mechanical couple members (34D and 108) on the base (111) and subassembly (8D), wherein the couple members on the base (111) are posts (34D) configured to couple with members (108) on the subassembly (8D), wherein the leaflets (6D) are axially spaced from the outflow rim of the base (111), such that the leaflets are not positioned in the tubular base body (see fig.38).

Allowable Subject Matter

Claims 18, 19, 21, 22, 24, 25, 26, 38, 39, and 43 are allowed.

Claim 54 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cheryl Miller



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